

REMARKS

I. Formal Matters

A. Status of Claims

Claims 1-5 and 7-17 are pending in the application. Claims 1-5 and 7-17 are rejected. Claims 8-15 and 17 are objected to.

After entry of the amendment, claims 1 and 2 will be pending, and claims 3-39 will be canceled. Claim 1 has been amended to incorporate the recitation of claim 17. Claim 2 has been amended to delete the alternative recitation of "prevention."

B. Information Disclosure Statements

A copy of the PTO Form SB/08 that accompanied the Information Disclosure Statement filed May 22, 2008 remains outstanding. The Examiner is requested, respectfully, to consider the cited references and return the signed PTO form SB/08.

II. Detailed Action

A. Election/Restriction

The Examiner acknowledges Applicants' election of the compound of claim 17, i.e., 4-(1-((4-methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2ylthio)butanoic acid, for examination on the merits. All pending claims read on the elected species.

B. Priority

The Examiner states that the application is only entitled to benefit of the actual U.S. filing date of February 17, 2006, because the international application and the priority document are not in English and the Examiner cannot read them.

For the following reasons Applicants submit, respectfully, that the application is entitled to benefit of the filing dates of the international application and of the priority document

The present application is a sworn translation of the international application, and, therefore, at a minimum, Applicants are entitled to an effective U.S. filing date of August 20, 2004. Also, Applicants do not need to file a translation of the priority document to perfect their claim to priority unless required to do so by the Examiner. However, no such requirement has been made. Thus all that is needed to perfect Applicants' claim to priority is that Applicants make the claim and that a certified copy of the priority document be filed. See 37 C.F.R. § 1.55(a)(1) and (2). These requirements have been met.

C. Claim Objections

Claim 17 is objected to under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP §608.01(n). Accordingly, claim 17 has not been further treated on the merits.

This objection is moot in view of the cancellation of claim 17.

D. Claim Rejections - 35 U.S.C. § 112

1. Claims 1-5 and 7-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner states that he is unable to ascertain from the instant specification

what the term “a glucose intolerance improving amount” encompasses. The Examiner requests clarification.

Claims 3-5 and 7-16 have been canceled. Thus the rejection is moot as to these claims.

Claim 1 recited a method for improving glucose intolerance. Therefore, in Applicants’ opinion it is clear that a “glucose intolerance improving amount” is an amount sufficient to improve glucose intolerance. Nonetheless, the phrase “a glucose intolerance improving amount” has been changed to the more conventional phrase, an “effective amount.”

2. Claims 2-4 and 8-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the claims recite a method for “prevention” of glucose intolerance.

Claims 3-4 and 8-16 have been canceled. Thus the rejection is moot as to these claims.

This rejection is overcome by amending claim 2 to delete reference to “prevention” of diseases.

E. Claim Rejections - 35 U.S.C. § 103

Claims 1-6 and 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishimura et al. (US Patent 6,410,576) in view of Tsuchiya et al. (European Patent Application EP 1 249 450), Iimura et al. (“Effects of Angiotensin Receptor Antagonist and Angiotensin Converting Enzyme Inhibitor on Insulin Sensitivity in Fructose-Fed Hypertensive Rats and Essential Hypertensives,” 1995, AJH, Volume 8, Pages 353-357 and cited by Applicant), Ishihara et al. (WIPO Document W001/12226 and cited by Applicant) and Nishimura et al. (WIPO Document WO 01/32621 and cited by Applicant, hereinafter Nishimura 1).

The Examiner cites Nishimura et al. as teaching that compounds that exhibit chymase inhibitory activity are “expected to be effective at treating diabetes complications” (columns 9, line 62 to column 10, line 17 and column 52, lines 17-22). The Examiner acknowledges that Nishimura et al. do not teach the specific diabetes complications recited in claims 4 and 5 or the underlying mechanism creating the complications, as recited in claims 1 and 2. In addition, the Examiner acknowledges that Nishimura et al. do not identify 4-(1-((4-methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2-ylthio)butanoic acid as a chymase inhibitor, as encompassed by claims 8-17.

As to the underlying mechanism, the Examiner states that if a compound treats diabetes complications, it necessarily treats the underlying mechanism.

Furthermore, the Examiner cites Tsuchiya et al. in order to compensate for other deficiencies of Nishimura et al. According to the Examiner, Tsuchiya et al. teach benzimidazole derivatives that inhibit human chymase and that are clinically applicable as a treating agent for various diseases associated with human chymase (page 2, paragraphs 1 and 7 and page 67, paragraph 238). The Examiner further asserts that Tsuchiya et al. teach that the benzimidazole derivatives have an extremely high chymase inhibitor activity and that one such disclosed derivative is 4-(1-((4-methylbenzo[b]thiophen-3-yl)methyl)benzimidazol-2-ylthio)butanoic acid (page 2, paragraph 5 and Page 8, compound 56 and Example 15, page 64).

The Examiner concludes that one of ordinary skill in the art would readily substitute the benzimidazole derivatives of Tsuchiya et al. for the chymase inhibitors of Nishimura et al. and expect that the compounds would treat glucose intolerance (claims 1 and 8-17) and diseases caused by glucose intolerance (claims 2, 3 and 8-17).

Imura et al. is cited as teaching the subject matter of claim 7.

Ishihara et al. is cited as teaching the subject matter of claim 5.

Nishimura 1 is cited as teaching the subject matter of claim 4.

Claims 3-6 and 7-16 have been canceled, making the rejection moot as to these claims.

With respect to amended claims 1 and 2, Applicants submit that the Examiner's rejection is being made in hindsight. That is, the references do not teach a relationship between chymase and glucose metabolism. In fact the Examiner admits that Nishimura et al. do not teach that chymase is involved in glucose metabolism. The Examiner instead just makes an unsupported assertion that if a compound treats a condition, it must treat the underlying cause of the condition. However, this is not necessarily so. Drugs often treat symptoms of diseases, not the underlying causes, and there is no disclosure in the cited references to lead one of ordinary skill in the art to believe that chymase inhibitors would be useful to treat glucose intolerance.

Accordingly, the Examiner is requested, respectfully, to reconsider and remove this rejection.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.111
Application No.: 10/568,711

Attorney Docket No.: Q93208

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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